REMARKS

In paragraph 3, on page 3 of the Office Action, the Examiner notes that no Information Disclosure Statement has been filed in the present application.

Applicants file simultaneously herewith an Information Disclosure Statement making of record the references previously made of record in the prior applications to which priority is claimed.

Claims 1-23 are pending in the application. The claims can be divided into the following three embodiments:

(A) Claim 1-8 and 21-23 of the present application are directed to a method for treating infection in a patient having an infection (i.e., an infectious disease).

(B) Claim 9-14 and 21-23 of the present application are directed a method of increasing the number of dendritic cells in a patient having an infection (i.e., an infectious disease).

(C) Claim 15-23 of the present application are directed to a method of augmenting immune responses in a patient having an infection (i.e., an infectious disease).

In paragraph 4, on page 2 of the Office Action, the Examiner contends that the effective filing date of the present claims is August 19, 2003, i.e., the filing date of U.S. Application No. 10/643,384 (the present application).

In addition, paragraph 7, on page 3 of the Office Action, the Examiner objects to the specification for failing to provide antecedent basis for the claimed subject matter, i.e., the Examiner contends that the specification does not teach "methods

of treating infection in patients having an infection." Thus, it appears that the Examiner contends that embodiment (A) above is not supported, while by his silence, the Examiner appears to admit that embodiments (B) and (C) are supported.

The Examiner is requested to note that the present application is a Divisional of U.S. Application No. 10/241,927, filed September 10, 2002, which is a Continuation of U.S. Application No. 09/444,027, filed November 19, 1999. Hence, the effective filing date of the present claims should be at least November 19, 1999.[1/]

The present specification, and thus also the specification of U.S. Application No. 10/241,927, and U.S. Application No. 09/444,027, disclose the situation where the antigen, such as a bacterial antigen or viral antigen, may already exist within the patient and that flt3-ligand may be administered as a vaccines adjuvant to enhance an immune response to the viral or bacterial antigen (see, e.g., page 17, lines 10 *et seq.* thereof). Thus, it is clear that the present specification, as well as the priority specification disclose treatment of infection, as the presence of the bacterial or viral antigen in

---

[1/] U.S. Appln. No. 09/444,027, filed November 19, 1999, is a CIP of 09/154,903, filed September 17, 1998 (now abandoned); which is a CIP of U.S. Appln. No. 08/725,540, filed October 3, 1996 (now abandoned); which is a CIP of U.S. Appln. No. 08/539,142, filed October 4, 1995 (now abandoned). Applicants also claim benefit of each of these prior applications. For example, U.S. Appln. No. 08/725,540 states (at page 3, line 34, et seq) that "The present invention provides a method of augmenting an immune response in a patient that has an infectious disease wherein the method comprises the step of administering an amount of flt3-ligand sufficient to increase the patient's number of dendritic cells." Similar disclosure can be found in the other priority applications.

the patient would arise as result of the patient being infected with the bacteria or virus.

In this regard, the Examiner is requested to note that original Claim 3 of U.S. Application No. 09/444,027 was directed to a method of augmenting an immune response in a patient which "has an infectious disease" (see also, page 4, lines 29 *et seq* thereof). Infectious diseases result from infection with a bacteria or viral (i.e., with an infectious agent).

Similarly, U.S. Application No. 10/241,927 teaches a method of augmenting an immune response in a patient which "has an infectious disease" (see also, page 4, lines 17 *et seq* thereof).

It appears that the basis for the Examiner's position is that the claims recite a method of "treating infection", whereas the disclosure is as to a method of augmenting an immune response in a patent having an infectious disease.

However, Applicants respectfully submit that these are one and the same, i.e., augmenting the immune response is against the bacterial or viral antigen, and this results in treating the infectious disease.

In any event, as noted above only Claims 1-14 (Embodiment (A)) are directed to a method of treatment, i.e., Claims 15-23 are directed to a method of increasing the number of dendritic cells in a patient having an infection (Embodiment (B)), and a method of augmenting the immune response in a patient having an infection (Embodiment (C)). Embodiments (B) and (C), have clear support in the specification, *inter alia*, at page 4, lines 5 *et seq*.

Nonetheless, the Examiner is requested to note Claims 1-14 have been amended to set forth that the treatment is by

augmenting the immune response. Further, the claims have been amended to refer to "infectious disease", rather than "infection".

In paragraph 5, on page 3 of the Office Action, the Examiner requests that Applicants identify the trademarks in the specification and correct any typographical errors therein.

Applicants are not aware of any trademarks or errors in the specification that need to be corrected.

In paragraph 9, on page 4 of the Office Action, the Examiner rejects Claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by McKenna et al.

Specifically, the Examiner states that McKenna et al teaches the use of flt3-ligand in immunization protocols, including its use as an adjuvant vaccine comprising a bacterial and viral antigens. The Examiner contends that the claim language does not appear to result in a manipulative difference in the method steps when compared to the prior art disclosure.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The disclosure which the Examiner relies upon in McKenna et al for anticipating the present claims is basically the same disclosure in the present application and in the priority documents. However, the Examiner has contended that this disclosure does not support the claims.

Applicants respectfully submit that the Examiner can not have it both ways, either the specification and the priority documents do support the claims, or McKenna et al is not anticipatory prior art.

As noted above, it is Applicants position that the priority documents do support the present claims. As a result, McKenna et al, which at best has a 102(e) date of November 19, 2002, is not effective prior art, as the present claims have an effective filing date of at least November 19, 1999.

Thus, Applicants request withdrawal of the Examiner's rejection.

In paragraph 10, on page 5 of the Office Action, the Examiner objects to Claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by Rosenthal et al.

Specifically, the Examiner states that Rosenthal et al teaches the use of flt3-ligand in immunization protocols, including it use as an adjuvant in vaccines comprising bacterial and viral antigens.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As note above, it is Applicants position that the priority documents do support the present claims. As a result, Rosenthal et al, which at best has a 102(e) date of June 26, 2000, is not effective prior art, as the present claims have an effective filing date of at least November 19, 1999.

Thus, Applicants request withdrawal of the Examiner's rejection.

In paragraph 11, on page 5 of the Office Action, the Examiner rejects Claims 1-9, 11-15 and 17-23 under 35 U.S.C. § 102(b) as being anticipated by Lyman et al.

Specifically, the Examiner states that Lyman et al teaches the use of flt3-ligand in pharmaceutical compositions, and that

such can be used in methods to stimulate T cell proliferation, as well as hemopoietic cells when treating patients with HIV.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Initially, Applicants note that the claims directed to treating a bacterial infection, i.e., Claims 10 and 16 have not been included in this rejection. For purposes of consistency Claim 2 should also not be included in this rejection.

In any event, in view of the amendments to the Claims to exclude HIV, Lyman et al does not anticipate the claims.

Thus, Applicants request withdrawal of the Examiner's rejection.

In paragraph 13, on page 6 of the Office Action, the Examiner rejects Claims 1-23 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 11-12 of co-pending U.S. Application No. 10/397,687.

In view of the abandonment of U.S. Application No. 10/397,687 in favor of the Divisional thereof, i.e., U.S. Application No. 11/510,651, the Examiner's rejection has been rendered moot.

In view of the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at the below-listed number on any matters which might arise.

Respectfully submitted,

Gordon Kit
Registration No. 30,764

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: February 6, 2007